

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

## SPECIFICATION AMENDMENTS

In accordance with the replacement Drawings submitted herewith, please amend paragraphs [0015]-[0016], [0046]-[0068], [0071]-[0074], [0077]-[0079], [0085]-[0086], [0090], [0096]-[0097], [0099], [00103]-[00104], [00106], [00110]-[00111], [00113], [00118]-[00119], [00123]-[00124], [00127], [00129], [00137]-[00138], [00140]-[00141], [00144], [00149]-[00150], [00153], [00159], [00164]-[00166], [00168]-[00172], [00175], and [00179] of the Specification as indicated below.

[0015] While the instrumentation described herein (e.g., the static trials, static trial holders, dynamic trial, inserter/impactors, repositioners/extractors, and leveler) will be discussed for use with the artificial intervertebral disc of ~~Figs. 1g-n~~ Figs. 13-20, such discussions are merely by way of example and not intended to be limiting of their uses. Thus, it should be understood that the tools can be used with any of the artificial intervertebral discs disclosed in the '160 and '528 applications, or any other artificial intervertebral disc having (or being modifiable or modified to have) suitable features therefor. Moreover, it is anticipated that the features of the artificial intervertebral disc (e.g., the angled flat surfaces and accompanying holes and inwardly facing baseplate surfaces) and/or the static trials (e.g., the cylindrical trunks and angled flat surfaces and opposing notches and accompanying holes) that are used by the tools discussed herein to hold and/or manipulate these devices (such features, it should be noted, were first shown and disclosed in the '356, '585, '267, '160, and/or '528 applications) can be applied, individually or collectively or in various combinations, to other trials, spacers, artificial intervertebral discs or other orthopedic devices as stand-alone innovative features for enabling such trials, spacers, artificial intervertebral discs, or other orthopedic devices to be more efficiently and more effectively held and/or manipulated by the tools described herein or by other tools having suitable features. In addition, it should be understood that the invention encompasses artificial intervertebral discs,

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**Docket No.:** F-291  
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spacers, trials (static or dynamic), and/or other orthopedic devices, that have one or more of the features disclosed herein, in any combination, and that the invention is therefore not limited to artificial intervertebral discs, spacers, trials, and/or other orthopedic devices having all of the features simultaneously.

[0016] More particularly with regard to the static trials described herein, a plurality of static trials are provided primarily for use in determining the appropriate size of an artificial intervertebral disc to be implanted (or whether a particular size of the artificial intervertebral disc can be implanted) into the distracted intervertebral space (e.g., the artificial intervertebral disc 160 of ~~Figs. 18-19~~ Figs. 13-20). Preferably, for each artificial intervertebral disc to be implanted, a plurality of sizes of the artificial intervertebral disc would be available. That is, preferably, a plurality of the same type of artificial intervertebral disc would be available, each of the plurality having a respective width and depth dimension combination that allows it to fit within a correspondingly dimensioned intervertebral space. For example, the plurality of artificial intervertebral discs could include artificial intervertebral discs having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 discs. Accordingly, preferably, each of the plurality of static trials for use with a particular plurality of differently sized artificial intervertebral discs would have a respective width and depth dimension set corresponding to the width and depth of a respective one of the plurality of differently sized artificial intervertebral discs. For example, the plurality of static trials for use with the set of artificial intervertebral discs described for example could include static trials having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 static trials. It should be understood that the artificial intervertebral discs and/or the static trials can be offered in a variety of dimensions without departing from the scope of the invention, and that the dimensions specifically identified and quantified herein are merely exemplary. Moreover, it should be understood that the set of static trials need not include the same number of trials for

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each artificial intervertebral disc in the set of artificial intervertebral discs, but rather, none, one, or more than one trial can be included in the trial set for any particular artificial intervertebral disc in the set.

[0046] ~~Figs. 1a-f~~Figs. 1-6 show front (~~Fig. 1a~~Fig. 1), side (~~Fig. 1b~~Fig. 2), perspective (~~Fig. 1e~~Fig. 3), top (~~Fig. 1d~~Fig. 4), bottom cutaway (~~Fig. 1e~~Fig. 5) and top cutaway (~~Fig. 1f~~Fig. 6) views of a static trial of the present invention. ~~Figs. 1aa-ff~~Figs. 7-12 show front (~~Fig. 1aa~~Fig. 7), side (~~Fig. 1bb~~Fig. 8), perspective (~~Fig. 1ee~~Fig. 9), top (~~Fig. 1dd~~Fig. 10), bottom cutaway (~~Fig. 1ee~~Fig. 11), and top cutaway (~~Fig. 1ff~~Fig. 12) views of an alternate static trial of the present invention.

[0047] ~~Figs. 1g-n~~Figs. 13-20 show front (~~Fig. 1g~~Fig. 13), side cutaway (~~Fig. 1h~~Fig. 14), top (~~Fig. 1i~~Fig. 15), side cutaway (~~Fig. 1j~~Fig. 16), bottom cutaway (~~Fig. 1k~~Fig. 17), top cutaway (~~Fig. 1l~~Fig. 18), bottom perspective (~~Fig. 1m~~Fig. 19), and top perspective (~~Fig. 1n~~Fig. 20) views of an exemplary artificial intervertebral disc of the present invention.

[0048] ~~Figs. 2a-k~~Figs. 21-31 show top (~~Fig. 2a~~Fig. 21), side (~~Fig. 2b~~Fig. 22), perspective (~~Fig. 2e~~Fig. 23), disassembly (~~Fig. 2d-j~~Figs. 24-30), and side cutaway (~~Fig. 2k~~Fig. 31) views of a static trial holder of the present invention.

[0049] ~~Figs. 2aa-ee~~Figs. 32-34 and ~~2kk~~44 show side (~~Fig. 2aa~~Fig. 32), top (~~Fig. 2bb~~Fig. 33), perspective (~~Fig. 2ee~~Fig. 34), and side cutaway (~~Fig. 2kk~~Fig. 44) views of an alternate static trial holder 2000 of the present invention. ~~Figs. 2dd1, 2dd2, 2dd3~~Figs. 35, 36, 37, and ~~2ee-ff~~38-39 show a sleeve of the alternate static trial holder 2000 in side (~~Fig. 2dd1~~Fig. 35), top (~~Fig. 2dd2~~Fig. 36), side cutaway (~~Fig. 2dd3~~Fig. 37), front (~~Fig. 2ee~~Fig. 38), and back (with partial cutaway) (~~Fig. 2ff~~Fig. 39) views. ~~Figs. 2gg-ii~~Figs. 40-42 show an extension of the alternate static trial holder 2000 in top (~~Fig.~~

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**Docket No.:** F-291  
**Dated:** 4/8/2004

~~Fig. 40~~), proximal cutaway (~~Fig. 2h~~~~Fig. 41~~), side (~~Fig. 2i~~~~Fig. 42~~), and distal cutaway (~~Fig. 2j~~~~Fig. 43~~) views.

[0050] ~~Figs. 2l-n~~~~Figs. 45-47~~ show top (~~Fig. 2l~~~~Fig. 45~~), side (~~Fig. 2m~~~~Fig. 46~~), and perspective (~~Fig. 2n~~~~Fig. 47~~) views of the alternate static trial holder of ~~Figs. 2aa-kk~~~~Figs. 32-44~~ holding an alternate static trial of ~~Figures 1aa-ff~~~~Figs. 7-12~~ from an anterior approach hold. ~~Figs. 2oo-pp~~~~Figs. 48-49~~ show top views of the alternate static trial holder of ~~Figs. 2aa-kk~~~~Figs. 32-44~~ holding an alternate static trial of ~~Figures 1aa-ff~~~~Figs. 7-12~~ from two anterior-lateral approach holds. ~~Fig. 2qq~~~~Fig. 50~~ shows a perspective view of the alternate static trial holder of ~~Figs. 2aa-kk~~~~Figs. 32-44~~ holding an alternate static trial of ~~Figures 1aa-ff~~~~Figs. 7-12~~ from the anterior-lateral approach hold of ~~Fig. 2pp~~~~Fig. 49~~.

[0051] ~~Figs. 3a-d~~~~Figs. 51-54~~ show side (~~Fig. 3a~~~~Fig. 51~~), top (~~Fig. 3b~~~~Fig. 52~~), side cutaway (~~Fig. 3c~~~~Fig. 53~~), and perspective (~~Fig. 3d~~~~Fig. 54~~) views of a dynamic trial of the present invention.

[0052] ~~Figs. 4a-d~~~~Figs. 55-58~~ show side (~~Fig. 4a~~~~Fig. 55~~), top (~~Fig. 4b~~~~Fig. 56~~), side cutaway (~~Fig. 4c~~~~Fig. 57~~), and perspective (~~Fig. 4d~~~~Fig. 58~~) views of an inserter/impactor of the present invention.

[0053] ~~Figs. 4e-h~~~~Figs. 59-62~~ show side (~~Fig. 4e~~~~Fig. 59~~), top (~~Fig. 4f~~~~Fig. 60~~), side cutaway (~~Fig. 4g~~~~Fig. 61~~), and perspective (~~Fig. 4h~~~~Fig. 62~~) views of an inserter/impactor of the present invention holding a static trial of the present invention.

[0054] ~~Figs. 4i-j~~~~Figs. 63-64~~ show top views of an inserter/impactor of the present invention holding a static trial of the present invention in two alternative ways.

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**Docket No.:** F-291  
**Dated:** 4/8/2004

[0055] ~~Figs. 4k-n~~ Figs. 65-68 show side (~~Fig. 4k~~ Fig. 65), top (~~Fig. 4l~~ Fig. 66), side cutaway (~~Fig. 4m~~ Fig. 67), and perspective (~~Fig. 4n~~ Fig. 68) views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention.

[0056] ~~Figs. 4o-p~~ Figs. 69-70 show top views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention in two alternative ways.

[0057] ~~Figs. 4aa-cc~~ Figs. 71-73 show side (~~Fig. 4aa~~ Fig. 71), perspective (~~Fig. 4bb~~ Fig. 72), and close-up perspective (~~Fig. 4cc~~ Fig. 73) views of a wedge plate inserter/impactor of the present invention.

[0058] ~~Figs. 4dd-4gg~~ Figs. 74-77 show bottom (~~Fig. 4dd~~ Fig. 74), side (~~Fig. 4ee~~ Fig. 75), top (~~Fig. 4ff~~ Fig. 76), and side cutaway (~~Fig. 4gg~~ Fig. 77) views of a distal end of a wedge plate inserter/impactor of the present invention.

[0059] ~~Figs. 4hh-ii~~ Figs. 78-79 show top (~~Fig. 4hh~~ Fig. 78) and side (~~Fig. 4ii~~ Fig. 79) views of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc.

[0060] ~~Figs. 4jj-ll~~ Figs. 80-82 show top (~~Fig. 4jj~~ Fig. 80), side (~~Fig. 4kk~~ Fig. 81), and side cutaway (~~Fig. 4ll~~ Fig. 82) views of a distal end of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc.

[0061] ~~Figs. 5a-e~~ Figs. 83-85 show side (~~Fig. 5a~~ Fig. 83), top (~~Fig. 5b~~ Fig. 84), and perspective (~~Fig. 5c~~ Fig. 85) views of a symmetric repositioner/extractor of the present invention.

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
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**Docket No.:** F-291  
**Dated:** 4/8/2004

[0062] ~~Figs. 5d-f~~Figs. 86-88 show side (~~Fig. 5d~~Fig. 86), top (~~Fig. 5e~~Fig. 87), and perspective (~~Fig. 5f~~Fig. 88) views of an offset left repositioner/extractor of the present invention.

[0063] ~~Figs. 5g-i~~Figs. 89-91 show side (~~Fig. 5g~~Fig. 89), top (~~Fig. 5h~~Fig. 90), and perspective (~~Fig. 5i~~Fig. 91) views of an offset right repositioner/extractor of the present invention.

[0064] ~~Figs. 5j-l~~Figs. 92-94 show side (~~Fig. 5j~~Fig. 92), top (~~Fig. 5k~~Fig. 93), and perspective (~~Fig. 5l~~Fig. 94) views of an alternative offset left repositioner/extractor of the present invention.

[0065] ~~Figs. 5m-o~~Figs. 95-97 show side (~~Fig. 5m~~Fig. 95), top (~~Fig. 5n~~Fig. 96), and perspective (~~Fig. 5o~~Fig. 97) views of an alternative offset right repositioner/extractor of the present invention.

[0066] ~~Figs. 5p-u~~Figs. 98-103 show exemplary various possible repositioner/extractor approach angles with a three hole configuration of the present invention.

[0067] ~~Figs. 5v-dd~~Figs. 104-112 show exemplary various possible repositioner/extractor approach angles with a four hole configuration of the present invention.

[0068] ~~Figs. 6a-e~~Figs. 113-117 show bottom (~~Fig. 6a~~Fig. 113), side (~~Fig. 6b~~Fig. 114), front (~~Fig. 6c~~Fig. 115), top partial perspective (~~Fig. 6d~~Fig. 116), and bottom partial perspective (~~Fig. 6e~~Fig. 117) views of a leveler of the present invention.

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**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

[0071] Referring now to ~~Figs. 1a-f~~Figs. 1-6, a static trial of the present invention is shown in front (~~Fig. 1a~~Fig. 1), side (~~Fig. 1b~~Fig. 2), perspective (~~Fig. 1e~~Fig. 3), top (~~Fig. 1d~~Fig. 4), bottom cutaway (~~Fig. 1e~~Fig. 5) and top cutaway (~~Fig. 1f~~Fig. 6) views. Referring now to ~~Figs. 1aa-ff~~Figs. 7-12, an alternate static trial of the present invention is shown in front (~~Fig. 1aa~~Fig. 7), side (~~Fig. 1bb~~Fig. 8), perspective (~~Fig. 1ee~~Fig. 9), top (~~Fig. 1dd~~Fig. 10), bottom cutaway (~~Fig. 1ee~~Fig. 11) and top cutaway (~~Fig. 1ff~~Fig. 12) views. Referring now to ~~Figs. 1g-n~~Figs. 13-20, an artificial intervertebral disc of the present invention is shown in front (~~Fig. 1g~~Fig. 13), side cutaway (~~Fig. 1h~~Fig. 14), top (~~Fig. 1i~~Fig. 15), side cutaway (~~Fig. 1j~~Fig. 16), bottom cutaway (~~Fig. 1k~~Fig. 17), top cutaway (~~Fig. 1l~~Fig. 18), bottom perspective (~~Fig. 1m~~Fig. 19), and top perspective (~~Fig. 1n~~Fig. 20) views.

[0072] It should be understood that the illustration and reference herein to the artificial intervertebral disc shown in ~~Figs. 1g-n~~Figs. 13-20 is merely to show an example of one type of artificial intervertebral disc that is contemplated by, encompassed by, and suitable for use with, the present invention, and that such illustration and reference herein is not meant to limit the scope of the present invention or limit the uses of the present invention. Rather, any other artificial intervertebral disc (or any other orthopedic device) having suitable features for being used with the instrumentation and methods described herein are contemplated by the present invention. Indeed, the features suitable for manipulation (e.g., the angled flat surfaces and adjacent holes and inwardly facing surfaces) are encompassed by the present invention, regardless of to what orthopedic device they may be applied. Other exemplary suitable artificial intervertebral discs include, but are not limited to, the artificial intervertebral discs described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). It should be noted that, as can be seen from ~~Figs. 1g-n~~Figs. 13-20, that the artificial intervertebral

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Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

disc shown in ~~Figs. 1g-n~~ Figs. 13-20 has features similar to those of these other suitable artificial intervertebral discs of the '160 and '528 applications, and it should be understood that such similar features are structurally and functionally as described in the '160 and '528 applications. Such similar features include an inwardly facing surface 164a of the upper baseplate 164a, and a convex structure 162 on the lower baseplate 168b, the convex structure 162 having an inwardly facing surface 164b.

[0073] And, while the instrumentation described herein (e.g., the static trials, static trial holders, dynamic trial, inserter/impactors, repositioners/extractors, and leveler) will be discussed for use with the artificial intervertebral disc of ~~Figs. 1g-n~~ Figs. 13-20, such discussions are merely by way of example and not intended to be limiting of their uses. Thus, it should be understood that the tools can be used with any of the artificial intervertebral discs disclosed in the '160 and '528 applications, or any other artificial intervertebral disc having (or being modifiable or modified to have) suitable features therefor. Moreover, it is anticipated that the features of the artificial intervertebral disc (e.g., the angled flat surfaces and accompanying holes and inwardly facing baseplate surfaces) and/or the static trials (e.g., the cylindrical trunks and angled flat surfaces and accompanying holes and/or engagement notches) that are used by the tools discussed herein to hold and/or manipulate these devices (such features, it should be noted, were first shown and disclosed in the '356, '585, '267, '160, and '528 applications) can be applied, individually or collectively or in various combinations, to other trials, spacers, artificial intervertebral discs or other orthopedic devices as stand-alone innovative features for enabling such trials, spacers, artificial intervertebral discs, or other orthopedic devices to be more efficiently and more effectively held and/or manipulated by the tools described herein or by other tools having suitable features. In addition, it should be understood that the invention encompasses artificial intervertebral discs, spacers, trials (static or dynamic), and/or other orthopedic devices, that have one or more of the features disclosed herein, in any combination, and that the invention is therefore not limited to artificial intervertebral



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**For:** Intervertebral Spacer Device  
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Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

discs, spacers, trials, and/or other orthopedic devices having all of the features simultaneously.

[0074] Referring to ~~Figs. 1a-f~~Figs. 1-6 and ~~1aa-ff~~7-12, a plurality of static trials 100,1000 are provided primarily for use in determining the appropriate size of an artificial intervertebral disc to be implanted (or whether a particular size of the artificial intervertebral disc can be implanted) into the distracted intervertebral space (e.g., the artificial intervertebral disc 160 of ~~Figs. 1g-n~~Figs. 13-20). Preferably, for each artificial intervertebral disc to be implanted, a plurality of sizes of the artificial intervertebral disc would be available. That is, preferably, a plurality of the same type of artificial intervertebral disc would be available, each of the plurality having a respective width and depth dimension combination that allows it to fit within a correspondingly dimensioned intervertebral space. For example, the plurality of artificial intervertebral discs could include artificial intervertebral discs having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 discs. Accordingly, preferably, each of the plurality of static trials 100,1000 for use with a particular plurality of differently sized artificial intervertebral discs would have a respective width and depth dimension set corresponding to the width and depth of a respective one of the plurality of differently sized artificial intervertebral discs. For example, the plurality of static trials 100,1000 for use with the set of artificial intervertebral discs described for example could include static trials having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 static trials. It should be understood that the artificial intervertebral discs and/or the static trials 100,1000 can be offered in a variety of dimensions without departing from the scope of the invention, and that the dimensions specifically identified and quantified herein are merely exemplary. Moreover, it should be understood that the set of static trials 100,1000 need not include the same number of trials for each artificial intervertebral disc in the set of artificial intervertebral discs,

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**For:** Intervertebral Spacer Device  
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Tool

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**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

but rather, none, one, or more than one trial can be included in the trial set for any particular artificial intervertebral disc in the set.

[0077] In some embodiments, while not shown in ~~Figs. 1a-f or Figs. 1aa-ff~~Figs. 1-6 or Figs. 7-12, it is also preferable that the annular groove 104,1040 radially widen outwardly, such that the walls 112,1120 of the annular groove 104,1040 are tapered toward one another with the increasing depth of the groove 104,1040, such that the floor 114,1140 of the groove 104,1040 is more narrow than the opening 116,1160 of the groove 104,1040. Accordingly, preferably, in such embodiments, each semicircular extent 216a-b,2160a-b correspondingly radially widens outwardly, such that the thinner portion of the extent 216a-b,2160a-b fits closer to the floor 114,1140 of the annular groove 104,1040, so that the tapered surfaces of the extents 216a-b,2160a-b compress against the tapered walls 112,1120 of the annular groove 104,1040 when the static trial 100,1000 is engaged by the static trial holder 200,2000. This taper locking provides for a secure grip so that the static trial 100,1000 can be manipulated accurately and efficiently.

[0078] In some embodiments, while not shown in ~~Figs. 1a-f or Figs. 1aa-ff~~Figs. 1-6 or Figs. 7-12, it is also preferable that the floor of the annular groove 104,1040 of the cylindrical trunk 106,1060 be ridged (e.g., have ridges that run parallel to the longitudinal axis of the cylindrical trunk), and the surfaces of the semicircular extents 216a-b,2160a-b of the static trial holder 200,2000 that compress against the floor of the annular groove 104,1040 when the static trial holder 200,2000 grips the static trial 100,1000 be correspondingly provided with ridges. The interlocking of the ridges of the static trial 100,1000 with the ridges of the static trial holder 200,2000 when the static trial 100,1000 is engaged prevents rotation of the static trial 100,1000 about the longitudinal axis of the cylindrical trunk 106,1060 with respect to the static trial holder 200,2000.

**Applicant(s):** Errico et al.  
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Tool

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**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

[0079] Preferably, as shown in ~~Figs. 1aa-ff~~Figs. 7-12, each alternate static trial 1000 includes (on any alternate static trial surface that faces the desired engagement approach direction of the alternate static trial holder 2000) opposing recesses, preferably formed as upper and lower notches, an upper notch in the upper baseplate and a lower notch in the lower baseplate. For example, opposing notches 1320b and 1320e are on each of the anteriorly facing flat surfaces of the upper 1080a and lower 1080b baseplates. And, for example, opposing notches 1320a and 1320d are on one of the anterior-laterally facing flat surfaces of the upper 1080a and lower 1080b baseplates. And, for example, opposing notches 1320c and 1320f are on the other of the anterior-laterally facing flat surfaces of the upper 1080a and lower 1080b baseplates. Preferably, the notches 1320a-f are sized so that the opposing notches of each pair (1320a,d, 1320b,e, and 1320c,f) form a volume that closely accommodates the dimensions of the alternate static trial holder's 2000 prongs' 2140a-b cross-section. That is, as described below, the body of each prong 2140a-b is thicker than the semicircular extent 2160a-b that extends from the body, and as such, whereas the semicircular extents 2160a-b fit into the annular groove 1040, the prongs 2140a-b do not because the depth 2260 of their cross-section (described below) is greater than the width of the annular groove opening 1160. However, each notch pair (1320a,d, 1320b,e, and 1320c,f) accommodates this greater thickness, in that each notch 1320a-f has a depth 1340, and, when the two notch depths 1340 of the opposing notches of the notch pair are taken together with the width of the annular groove 1040, the combined distance accommodates the depth 2260 of the static trial holder's 2000 prongs' 2140a-b cross-section. Further, each notch 1320a-f has a width 1360 that accommodates the width 2240 of the alternate static trial holder's 2000 prongs' 2140a-b cross-section. (It should be noted that the width 1360 accommodates the width 2240 of the alternate static trial holder's 2000 prongs' 2140a-b cross-section even when the prongs 2140a-b are separated to place the holding enclosure 2100 in an expanded state as described below. This enables the notches 1320a-f to accommodate the width 2240 of the prongs' cross-section as the cylindrical trunk 1060 of the static trial 1000 is being snapped into

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
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**For:** Intervertebral Spacer Device  
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Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

the holding enclosure 2100 as described below.) As such, as the opposing semicircular extents 2160a-b of the alternate static trial holder 2000 are placed into the annular groove 1040, the bodies of the prongs 2140a-b pass into the notches of the pair so that the semicircular extents 2160a-b can continue into the annular groove 1040 and be seated around the cylindrical trunk 1060. More specifically, the prongs 2140a-b of the alternate static trial holder 2000 fit into the notches above and below it (e.g., 1320b and 1320e for an anterior approach; 1320a and 1320d for an anterior-lateral approach; and 1320c and 1320f for another anterior-lateral approach). Once the prongs 2140a-b are fitted within the notch pair, interference between the prongs 2140a-b and the notch walls limits or prevents rotation of the alternate static trial 1000 about a longitudinal axis (e.g., an axis parallel to the longitudinal axis of the cylindrical trunk 1060) with respect to the alternate static trial holder 2000.

[0085] Preferably, both of the baseplates of the static trial 100,1000 or disc 160 have similarly configured flat surfaces. For example, the lower baseplate's 108b,1080b,168b flat surfaces 120a-c,1200a-c,180a-c have similarly configured and similarly oriented counterpart flat surfaces 120d-f,1200d-f,180d-f on the upper baseplate 108a,1080a,168a. Further preferably, both baseplates' 108a-b,1080a,168a-b flat surfaces 120a-f,1200a-f,180a-f face the angled flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 when the static trial 100,1000 or disc 160 is held by the inserter/impactor 400,4000. For example, in an anterior approach for the trial 100,1000 (as shown in ~~Figs. 4e-h~~ Figs. 59-62, showing the trial 100 being held by the inserter/impactor 400 as an example for of how either trial 100,1000 can be held by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420a (or 4200a and 4200d), 120b,1200b and 120e,1200e facing 420b (or 4200b and 4200e), and 120c,1200c and 120f,1200f facing 420c (or 4200c and 4200f), and in an anterior approach for the disc 160 (as shown in ~~Figs. 4k-n~~ Figs. 65-68, showing the disc 160 being held by the inserter/impactor 400 as an example for of how the disc 160 can be held by either inserter/impactor 400,4000), 180a and 180d facing 420a (or 4200a and

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

4200d), 180b and 180e facing 420b (or 4200b and 4200e), and 180c and 180f facing 420c (or 4200c and 4200f).

[0086] It should be noted that preferably, when the static trial 100,1000 is held by the inserter/impactor 400,4000, the flat surfaces 120a-c, 1200a-c and the counterpart flat surfaces 120d-f, 1200d-f are tightly held against the angled flat surfaces 420a-c, 4200a-f of the inserter/impactor 400,4000 as described above. It is also preferable that the baseplates 108a-b, 1080a-b of each of the plurality of static trials 100,1000 be appropriately lordotically angled relative to one another to ease insertion of the static trial 100,1000 into the intervertebral space and to mimic how the artificial intervertebral disc 160 will typically be oriented as it is being inserted using the inserter/impactor 400,4000. While not shown in ~~Figs. 1a-f or Figs. 1aa-ff~~ Figs. 1-6 or Figs. 7-12, in some embodiments, when the static trials 100,1000 are formed in such a lordotically oriented configuration, it is preferable that the flat surfaces 120d-f, 1200d-f on the first (e.g., upper) baseplate 108a, 1080a be parallel to the flat surfaces 120a-c, 1200a-c of the second (e.g., lower) baseplate 108b, 1080b in the static trial's 100,1000 appropriately lordotically oriented configuration, so that when the static trial 100,1000 is held tightly by the inserter/impactor 400,4000, the flat surfaces 120a-f, 1200a-f are flush with the flat surfaces 420a-c, 4200a-f of the inserter/impactor 400,4000 even though the baseplates 108a-b, 1080a-b are lordotically angled with respect to one another.

[0090] In order to provide for a holding of the static trial 100,1000 or disc 160 for two additional (here, anteriolateral) insertion approaches, each static trial 100,1000 or disc 160 also preferably includes two additional holes 122a, 1220a, 182a and 122c, 1220c, 182c, one (e.g., 122a, 1220a, 182a) spaced apart from one of the anteriolaterally facing flat surfaces (e.g., 120a, 1200a, 180a), and the other (e.g., 122c, 1220c, 182c) spaced apart from the other of the anteriolaterally facing flat surfaces (e.g., 120c, 1200c, 180c). Accordingly, operation of the inserter/impactor 400,4000 can

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

fit the holding pin 408,4080 into either of these two additional holes 122a,1220a,182a or 122c,1220c,182c, and hold the associated anteriolaterally facing flat surface (the one associated with the hole into which the pin 408,4080 is fit) of the static trial 100,1000 or disc 160 against the flat surface of the inserter/impactor 400,4000 opposite the pin 408,4080. For example, in a first anteriolateral approach for the trial 100,1000 (as shown in ~~Fig. 4~~Fig. 63 as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d not confronted, 120b,1200b and 120e,1200e facing 420a (or 4200a and 4200d), and 120c,1200c and 120f,1200f facing 420b (or 4200b and 4200e), and a first anteriolateral approach for the disc 160 (as shown in ~~Fig. 4~~Fig. 69 as an example of the how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d not confronted, 180b and 180e facing 420a (or 4200a and 4200d), and 180c and 180f facing 420b (or 4200b and 4200e). And, for example, in a second anteriolateral approach for the trial 100 (as shown in ~~Fig. 4~~Fig. 64 as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420b (or 4200b and 4200e), 120b,1200b and 120e,1200e facing 420c (or 4200c and 4200f), and 120c,1200c and 120f,1200f not confronted, and a second anteriolateral approach for the disc 160 (as shown in ~~Fig. 4~~Fig. 70 as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420b (or 4200b and 4200e), 180b and 180e facing 420c (or 4200c and 4200f), and 180c and 180f not confronted.

[0096] As described in greater detail below, three repositioner/extractors are illustrated and described (symmetric, offset left, and offset right) for example, and, for example, two hole configurations are illustrated and described. Referring again to ~~Figs. 1a-n~~Figs. 1-20 and ~~Figs. 1a-n~~Figs. 7-12, a first hole configuration includes the hole configuration described above, that is, three holes on one of the baseplates (e.g., the lower baseplate 108b,1080b,168b), the holes being configured so that a first hole 122b,1220b,182b is located in the anterior-posterior plane, and the adjacent (second

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

122a,1220a,182a and third 122c,1220c,182c) holes are located in respective opposing anteriolateral planes on either side of the first hole 122b,1220b,182b. (This hole configuration is also shown in ~~Figs. 5p-u~~Figs. 98-103, each of which shows a top cutaway view of the artificial intervertebral disc 160 of ~~Figs. 1g-n~~Figs. 13-20, showing its lower baseplate 168b, having the first hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the lower baseplate 168b shows the first hole 182b, the second hole 182a, and the third hole 182c of the first hole configuration.)

[0097] Referring again to ~~Figs. 1a-n~~Figs. 1-20, a second hole configuration includes four holes on one of the baseplates (e.g., the upper baseplate 108a,168a), the holes being configured so that first (e.g., 130c,190c) and second (e.g., 130b,190b) holes straddle the anterior-posterior plane, a third hole (e.g., 130d,190d) is located so that the third hole and the first hole straddle one of the opposing anteriolateral planes, and a fourth hole (e.g., 130a,190a) is located so that the fourth hole and the second hole straddle the other of the opposing anteriolateral planes. While this second hole configuration is not illustrated with regard to the static trials 1000, it should be understood that the static trials 1000 can be configured with such second hole configuration, or any other hole configuration, without departing from the scope of the present invention. (It should be noted that, while the opposing notches of the static trials 1000 are shown formed in conjunction with the holes in the baseplates, neither the number nor the placement of the opposing notches need coincide or be related to the number or placement of the holes in the baseplates.) (This second hole configuration is also shown in ~~Figs. 5v-d~~Figs. 104-112, each of which shows a bottom cutaway view of the artificial intervertebral disc of ~~Figs. 1g-n~~Figs. 1-20, showing its upper baseplate 168a, having the second hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the upper baseplate shows the first hole 190c, the second hole 190b, the third hole 190d, and the fourth hole 190a, of the second hole configuration.)

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

[0099] Thus, it can be seen that each of the repositioner/extractors can be used in more than one manner depending on the tool desired and the approach desired. These manners are described in greater detail below and illustrated in ~~Figs. 5p-dd~~Figs. 98-112 with regard to the detailed description of the repositioners/extractors.

[00103] Referring to ~~Figs. 2a-e~~Figs. 21-23 and ~~2k~~31, a static trial holder 200 of the present invention is shown in side (~~Fig. 2a~~Fig. 21), top (~~Fig. 2b~~Fig. 22), perspective (~~Fig. 2c~~Fig. 23), and side cutaway (~~Fig. 2k~~Fig. 31) views. In addition, referring to ~~Figs. 2d-f~~Figs. 24-26, a sleeve of the static trial holder is shown in side cutaway (~~Fig. 2d~~Fig. 24), front (~~Fig. 2e~~Fig. 25), and back (with partial cutaway) (~~Fig. 2f~~Fig. 26) views. In addition, referring to ~~Figs. 2g-i~~Figs. 27-29, an extension of the static trial holder is shown in top (~~Fig. 2g~~Fig. 27), proximal cutaway (~~Fig. 2h~~Fig. 28), side (~~Fig. 2i~~Fig. 29), and distal cutaway (~~Fig. 2j~~Fig. 30) views.

[00104] Referring to ~~Figs. 2aa-ee~~Figs. 32-34 and ~~2kk~~44, an alternate static trial holder 2000 of the present invention is shown in side (~~Fig. 2aa~~Fig. 32), top (~~Fig. 2bb~~Fig. 33), perspective (~~Fig. 2ee~~Fig. 34), and side cutaway (~~Fig. 2kk~~Fig. 44) views. In addition, referring to ~~Figs. 2dd1, 2dd2, 2dd3~~Figs. 35, 36, 37, and ~~2ee-ff~~38-39, a sleeve of the alternate static trial holder 2000 is shown in side (~~Fig. 2dd1~~Fig. 35), top (~~Fig. 2dd2~~Fig. 36), side cutaway (~~Fig. 2dd3~~Fig. 37), front (~~Fig. 2ee~~Fig. 38), and back (with partial cutaway) (~~Fig. 2ff~~Fig. 39) views. In addition, referring to ~~Figs. 2gg-ii~~Figs. 40-42, an extension of the alternate static trial holder 2000 is shown in top (~~Fig. 2gg~~Fig. 40), proximal cutaway (~~Fig. 2hh~~Fig. 41), side (~~Fig. 2ii~~Fig. 42), and distal cutaway (~~Fig. 2jj~~Fig. 43) views.

[00106] More specifically, each static trial holder 200,2000 includes a handle 202,2020, an extension 204,2040, and a sleeve 206,2060. As shown in ~~Fig. 2k~~Fig. 31 and ~~2kk~~44, the handle 202,2020 and the extension 204,2040 are fixed to one another



**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

(preferably by the distal end of the handle 202,2020 being fixed to the proximal end of the extension 204,2040) to form a shaft 208,2080. The sleeve 206,2060 surrounds the extension 204,2040 and is rotatable with respect to the handle 202,2040 and the extension 204,2040 about the longitudinal axis of the shaft 208,2080. The handle 202,2020 preferably has an flange 232,2320 at its proximal end for use in applying a distally or proximally directed force to position the static trial 100,1000 (or distraction spacer) into or out of the intervertebral space, and/or for use in helping the surgeon rotate the sleeve 206,2060 with respect to the extension 204,2040 (by engaging the flange 232,2320 and the control knob 219,2190 described below).

[00110] In some embodiments, while not shown in ~~Figs. 1a-f or Figs. 1aa-ff or Figs. 2a-k or Figs. 2aa-kk~~ Figs. 1-6 or Figs. 7-12 or Figs. 21-31 or Figs. 32-44, it is preferable that the annular groove 104,1040 radially widen outwardly, such that the walls of the annular groove 104,1040 taper toward one another with the increasing depth of the groove, such that the floor of the groove is more narrow than the opening 116,1160 of the groove. Accordingly, preferably, in such embodiments, each semicircular extent 216a-b,2160a-b correspondingly radially widens outwardly, such that the thinner portion of the extent 216a-b,2160a-b fits closer to the floor of the annular groove 104,1040, so that the tapered surfaces 215a-b,2150a-b of the extents 216a-b,2160a-b compress against the tapered walls of the annular groove 104,1040 when the static trial 100,1000 is engaged by the static trial holder 200,2000. This taper locking provides for a secure grip so that the static trial 100,1000 can be manipulated accurately and efficiently.

[00111] In some embodiments, while not shown in ~~Figs. 1a-f or Figs. 1aa-ff or Figs. 2a-k or Figs. 2aa-kk~~ Figs. 1-6 or Figs. 7-12 or Figs. 21-31 or Figs. 32-44, it is also preferable that the floor of the annular groove 104,1040 of the cylindrical trunk 106,1060 be ridged (e.g., have ridges that run parallel to the longitudinal axis of the cylindrical trunk), and the surfaces of the semicircular extents 216a-b,2160a-b of the

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

static trial holder 200,2000 that compress against the floor of the annular groove 104,1040 when the static trial holder 200,2000 engages the static trial 100,1000 be correspondingly provided with ridges. The interlocking of the ridges of the static trial 100,1000 with the ridges of the static trial holder 200,2000 when the static trial 100,1000 is engaged prevents rotation of the static trial 100,1000 about the longitudinal axis of the cylindrical trunk 106,1060 with respect to the static trial holder 200,2000.

[00113] More particularly, the prongs 214a-b,2140a-b can be brought together (or brought closer to one another; it should be understood that they need not touch to be encompassed by the present invention), to lock the holding enclosure 210,2100, by a rotation of the sleeve 206,2060 with respect to the handle 202,2020 and the extension 204,2040 about the longitudinal axis of the shaft 208,2080. A rotation control knob 219,2190 is provided to ease the rotation of the sleeve 206,2060. As shown in ~~Figs. 2g~~Figs. 27 and 2i~~29-30~~ in view of ~~Figs. 2d-e~~Figs. 24-25 and ~~Figs. 2g~~Figs. 40 and 2ii~~42-43~~ in view of ~~Figs. 2dd-ee~~Figs. 35-38, the bore 218,2180 of the sleeve 206,2060 (shown in cutaway in ~~Figs. 2e~~Figs. 25 and 2ee~~38~~) defines a cross-section that has a width 220,2200 that is greater than its depth 222,2220. Further as shown in those figures, the prongs 214a-b,2140a-b when separated (shown in cutaway in ~~Figs. 2j~~Figs. 30 and 2jj~~43~~) define a cross-section having a width 224,2240 that is greater than its depth 226,2260, the width 224,2240 and depth 226,2260 of the prongs' cross-section being closely accommodated by the width 220,2200 and depth 222,2220 of the bore's cross-section. When the prongs 214a-b,2140a-b are together, the width of prongs' cross-section is closely accommodated by the depth 222,2220 of the bore's cross-section. Thus, when the sleeve 206,2060 is rotated with respect to the extension 204,2040, the sides of the bore defining the depth 222,2220 of its cross-section bear against the sides of the prongs 214a-b,2140a-b defining the width of their cross-section.

[00118] Further, with regard to the alternate static trial holder 2000, the sleeve 2060 preferably has on its exterior surface at least one stop protrusion 1380 that is

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

positioned and dimensioned to extend dorsally or ventrally from the exterior surface when the holding enclosure is in its "locked" state (see ~~Figs. 21-44~~ Figs. 45-50), so that when the surgeon inserts the static trial 100,1000 into the intervertebral space, the stop protrusions 1380 prevent the static trial 100,1000 from being inserted too far into the space (that is, so that the stop protrusions 1380 hit against the lips of the adjacent vertebral body endplates before the static trial 100,1000 is inserted too far). It should be understood that stop protrusions can be applied to the static trial holder 200 without departing from the scope of the invention.

[00119] Accordingly, the static trials 100,1000 of the invention (or distraction spacers such as those disclosed in the '127 application) can be held and manipulated with either static trial holder 200,2000, and from a variety of approach angles. Holding the handle 202,2020 of the static trial holder 200,2000 in one hand, an operator can push the cylindrical trunk 106,1060 of the static trial 100,1000 (or the distraction spacer) against the mouth 213,2130 of the holding enclosure 210,2100 with enough force to temporarily expand the mouth 213,2130 to a width that will accommodate the diameter of the cylindrical trunk 106,1060 for passage through the mouth 213,2130. The radially inward tapering of the sides of the mouth 213,2130 (the facing ends 215a-b, 2150a-b of the semicircular extents 216a-b, 2160a-b of the prongs 214a-b, 2140a-b) facilitates this insertion. It should be noted that, with regard to the alternate static trial holder 2000, as shown in ~~Figs. 21-44~~ Figs. 45-50 with reference to ~~Figs. 1a-4a~~ Figs. 7 and 2jj43, the depth 2260 of the prongs' cross-section is closely accommodated by the depth of the opening establishing by the width of the annular groove 1020 of the alternate static trial 1000 and the depths 1340 of the notches in the pair of opposing notches (1320a,d, 1320b,d, or 1320c,f), and the width 2240 of the prongs' cross-section is accommodated by the width 1360 of the notches in the pair of opposing notches (1320a,d, 1320b,d, or 1320c,f), so that the prongs' cross-section fits into the opposing notches as, and when, the cylindrical trunk 1060 is surrounded by the semicircular extents 2160a-b. (That is, that the width 1360 of the notch pair accommodates the

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

width 2240 of the static trial holder's 2000 prongs' 2140a-b cross-section even when the prongs 2140a-b are separated to place the holding enclosure 2100 in an expanded state as described below. This enables the notch pair to accommodate the width 2240 of the prongs' cross-section as the cylindrical trunk 1060 of the static trial 1000 is being snapped into the holding enclosure 2100.)

[00123] Further with regard to the static trial holder 2000 engaging the static trials 1000, the interference between the prongs 2140a-b and the opposing notches in the notch pair in which the prongs 2140a-b are disposed prevents rotation of the static trial 1000 about a longitudinal axis (e.g., an axis parallel to the longitudinal axis of the cylindrical trunk 1060) with respect to the static trial holder 2000. That is, if the static trial 1000 is encouraged, by forces encountered during manipulation of the static trial 1000, to rotate about such an axis with respect to the static trial holder 2000, the side walls of the notches will be confronted by the prong 2140a-b bodies and such rotational movement of the static trial 1000 will be stopped. (As can be seen in the Figs. 3a-47, the prongs 2140a-b are too deep to fit into the annular groove 1060 without the notch pair accommodating their depth.) The same will happen if a reverse rotation about such an axis is attempted.

[00124] Further with regard to the static trial holder 2000, once the static trial 100,1000 has been inserted and removed from the intervertebral space (or the distraction spacer has been inserted and removed from the intervertebral space after being used to distract the space), the operator can unlock the holding enclosure 2100 by reverse rotating the sleeve 2060 (with enough initial force to overcome the biasing of the fitting of the bore's and the prongs' surfaces) ninety degrees. Again, as the sleeve 2060 rotates, the sides of the sleeve's bore's inner surface move away from the curved outer surfaces of the prongs 2140a-b and allow the prongs 2140a-b to separate (under their own bias toward the neutral position) as they are accommodated by the width 2200 of the bore 2180. When the prongs 2140a-b are separated and allowed to remain in that

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

position by the maintenance of the sleeve 2060 in the new position (with the head of the dog headed screw against the wall of the groove 2280 at the other end of the groove 2280), the semicircular extents 2160a-b are separated from one another and hold the cylindrical trunk 106,1060 against falling or slipping out. That is, the cylindrical trunk 106,1060 can be removed by the operator if the operator applies a sufficient force to widen the mouth 2130 of the holding enclosure 2100 enough to let the cylindrical trunk 106,1060 pass through the mouth 2130. Once the static trial 100,1000 (or distraction spacer) is removed, another one can be inserted and manipulated if required. As shown in ~~Figs. 200-204~~ Figs. 48-50, in addition to the anterior approach angle shown in ~~Figs. 211-214~~ Figs. 45-47, the illustrated notch configuration accommodates two anterior-lateral approach angles as well.

[00127] Referring now to ~~Figs. 3a-d~~ Figs. 51-54, a dynamic trial of the present invention is shown in top (~~Fig. 3a~~ Fig. 51), side (~~Fig. 3b~~ Fig. 52), side cutaway (~~Fig. 3c~~ Fig. 53) and perspective (~~Fig. 3d~~ Fig. 54) views.

[00129] More specifically, the dynamic trial 300 includes a shaft 302 having a bifurcated trial 304 at a distal end of the shaft 302. The trial 304 has an exterior that is preferably formed like the artificial intervertebral disc that it is meant to approximate. Accordingly, each half 306a-b of the bifurcated trial 304 has on its outwardly facing surface a convex dome 308a-b that is shaped like the convex dome of the corresponding baseplate of the artificial intervertebral disc that the dynamic trial 300 approximates (e.g., the convex domes 184a-b of the baseplates 168a-b of the artificial intervertebral disc 160 of ~~Figs. 1g-h~~ Figs. 13-20). Preferably, each convex dome 308a-b is smooth, rather than having a porous coating that is preferred for the convex domes 184a-b of the artificial intervertebral disc 160, and each half 306a-b does not have stabilizing spikes such as the stabilizing spikes 188a-b on the outwardly facing surfaces 186a-b of the artificial intervertebral disc 160. The omission of these device stabilizing and bone ingrowth encouraging structures and surfaces on the dynamic trial

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

300 enables the surgeon to test the size of the artificial intervertebral disc 160 to be implanted without invading the vertebral body endplates. The shaft 302 includes an inner shaft portion 310 that centrally divides at a fulcrum 311 into upper and lower distal extensions 312a-b. The lower distal extension 312b is fixed to the upper distal extension 312a at the fulcrum 311, preferably by screws 313a-b that are plug welded in place. Preferably, as shown, at least the most proximal screw 313b extends above the top surface of the upper distal extension 312a to serve as a backup stop to prevent extreme forward movement of the control knob 318 that is operated to separate the distal extensions 312a-b (described below).

[00137] Referring now to ~~Figs. 4a-d~~Figs. 55-58, an inserter/impactor of the present invention is shown in side (~~Fig. 4a~~Fig. 55), top (~~Fig. 4b~~Fig. 56), side cutaway (~~Fig. 4c~~Fig. 57) and perspective (~~Fig. 4d~~Fig. 58) views. ~~Figs. 4e-h~~Figs. 59-62 show side (~~Fig. 4e~~Fig. 59), top (~~Fig. 4f~~Fig. 60), side cutaway (~~Fig. 4g~~Fig. 61), and perspective (~~Fig. 4h~~Fig. 62) views of an inserter/impactor of the present invention holding a static trial of the present invention. ~~Figs. 4i-j~~Figs. 63-64 show top views of an inserter/impactor of the present invention holding a static trial of the present invention in two alternative ways. ~~Figs. 4k-n~~Figs. 65-68 show side (~~Fig. 4k~~Fig. 65), top (~~Fig. 4l~~Fig. 66), side cutaway (~~Fig. 4m~~Fig. 67), and perspective (~~Fig. 4n~~Fig. 68) views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention. ~~Figs. 4o-p~~Figs. 69-70 show top views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention in two alternative ways.

[00138] Referring now to ~~Figs. 4aa-ll~~Figs. 71-82 side (~~Fig. 4aa~~Fig. 71), perspective (~~Fig. 4bb~~Fig. 72), and close-up perspective (~~Fig. 4cc~~Fig. 73) views of a wedge plate inserter/impactor of the present invention. ~~Figs. 4dd-gg~~Figs. 74-77 show bottom (~~Fig. 4dd~~Fig. 74), side (~~Fig. 4ee~~Fig. 75), top (~~Fig. 4ff~~Fig. 76), and side cutaway (~~Fig. 4gg~~Fig. 77) views of a distal end of a wedge plate inserter/impactor of the present

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

invention. ~~Figs. 4hh-ii~~Figs. 78-79 show top (~~Fig. 4hh~~Fig. 78) and side (~~Fig. 4ii~~Fig. 79) views of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc. ~~Figs. 4jj-ll~~Figs. 80-82 show top (~~Fig. 4jj~~Fig. 80), side (~~Fig. 4kk~~Fig. 81), and side cutaway (~~Fig. 4ll~~Fig. 82) views of a distal end of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc.

[00140] More particularly, the inserter/impactor 400,4000 includes a shaft 402,4020 having a distal end 404,4040 that has angled flat surfaces 420a-c,4200a-f corresponding to and fittable against angled flat surfaces of the static trial (e.g., the surfaces 120a-f,1200a-f of the static trial 100,1000) or artificial intervertebral disc (e.g., the surfaces 180a-f of the artificial intervertebral disc 160) to be implanted. For example, in an anterior approach for the trial 100,1000 (as shown in ~~Figs. 4e-h~~Figs. 59-62 as an example of how either static trial 100,10000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420a (or 4200a and 4200d), 120b,1200b and 120e,1200e facing 420b (or 4200b and 4200e), and 120c,1200c and 120f,1200f facing 420c (or 4200c and 4200f), and in an anterior approach for the disc 160 (as shown in ~~Figs. 4k-n~~Figs. 65-68 as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420a (or 4200a and 4200d), 180b and 180e facing 420b (or 4200b and 4200e), and 180c and 180f facing 420c (4200c and 4200f). Additionally with regard to the wedge plate inserter/impactor 4000, the distal end 4040 has a wedge-shaped extension 4042 including upper 4200g and lower 4200h wedge surfaces corresponding to and fittable against the inwardly facing surfaces of the artificial intervertebral disc (e.g., the lower surface 164a of the upper baseplate 168a of the disc 160, and the upper surface 164b of the lower baseplate 168b of the disc 160, respectively) to be implanted, causing the baseplates to be angled at a 15 degree lordosis angle, with the lower surface 164a of the upper baseplate 168a held against the upper surface 4200g, and the upper surface of

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

the shield being held against the lower surface 4200h, as best shown in ~~Figs. 4hh-II~~Figs. 78-82

[00141] In particular with regard to the wedge plate inserter/impactor 4000, the inserter/impactor 4000 holds the disc 160 in a preferred position with respect to the inserter/impactor 4000. (It should be understood that the surfaces of the wedge-shaped extension 4042 can be modified within the scope of the present invention to hold the disc 160 (or another orthopedic device) at positions other than those illustrated herein.) In the illustrated embodiment of the inserter/impactor 4000 in use with the disc 160, the preferred position is with the baseplates 168a,b of the disc 160 angle at 15 degrees of lordosis with respect to one another. More particularly, as best shown in ~~Figs. 4hh-II~~Figs. 78-82, preferably, the upper and lower surfaces (e.g., 4200g and 4200h) of the wedge-shaped extension 4042 protrude from the distal end 4040 and are formed to hold the baseplates 168a,b such that they are angled at 15 degrees of lordosis with respect to one another. A surface (e.g., lower surface 4200h) of the wedge-shape extension 4042 that mates with an inwardly facing surface of a baseplate (e.g., the lower baseplate 168b) of a disc (e.g., 160) may be correspondingly shaped (e.g., curved or flat) for interaction or mating with the disc baseplate (e.g., the lower surface 4200h of the wedge-shaped extension as illustrated is curved to accommodate the surface of the shield of the disc). Preferably, the forward surface 4200i of the wedge-shaped extension 4042 has a concave curvature towards the shaft 4020 of the inserter/impactor 4000, also for accommodating the curvature of the surface of the shield of the disc.

[00144] A flange 411,4110, mechanically connected to the pin 408,4080 and translating adjacent the shaft 402,4020, can be pushed distally to overcome the bias of the spring 409,4090 to space the pin 408,4080 away from the central flat surface 420b,4200b. (An alternative configuration is one in which the flange 411,4110 and the pin 408,4080 are formed from a single piece, rather than being mechanically connected.)



**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

In this extended position, the pin 408,4080 can be inserted in the hole 122b,1220b,182b in the baseplate 108b,1080b,168b of the static trial 100,1000 or artificial intervertebral disc 160. Releasing the flange 411,4110 allows the spring 409,4090 to pull the pin 408,4080 back, causing the anteriorly facing surface 120b,1200b,180b of the baseplate 108b,1080b,168b to be held against the central flat surface 420b of the inserter/impactor 400 (or against the lower central flat surface 4200b of the inserter/impactor 4000) and the anterioloaterally facing flat surfaces 120a,c,1200a,c,180a,c of the static trial 100,1000 or artificial intervertebral disc 160 to be held against the other corresponding flat surfaces 420a,c of the inserter/impactor 400 (or against the other corresponding flat surfaces 4200a,c of the inserter/impactor 4000). Further and simultaneously, with regard to the wedge plate inserter/impactor 4000, the anteriorly facing surface 180e of the baseplate 168a is pulled against the upper central flat surface 4200e of the inserter/impactor 4000 and the anterioloaterally facing flat surfaces 180d,f of the artificial intervertebral disc 160 is pulled against the other corresponding flat surfaces 4200d,f of the inserter/impactor 4000. Additionally with regard to the wedge plate inserter/impactor 4000, as noted above, the upper and lower wedge surfaces (4200g,h) interfere between the inwardly facing surfaces 164a,b of the disc baseplates, causing the baseplates to be angled at a 15 degree lordosis angle, with the lower surface 164a of the upper baseplate 168a held against the upper surface 4200g, and the upper surface of the shield being held against the lower surface 4200h, as best shown in ~~Figs. 4h-h~~ Figs. 78-82.

[00149] Preferably, both of the baseplates of the static trial 100,1000 or disc 160 have similarly configured flat surfaces. For example, the lower baseplate's 108b,1080b,168b flat surfaces 120a-c,1200a-c,180a-c have similarly configured and similarly oriented counterpart flat surfaces 120d-f,1200d-f,180d-f on the upper baseplate 108a,1080a,168a. Further preferably, both baseplates' 108a-b,1080a-b,168a-b flat surfaces 120a-f,1200a-f,180a-f face the angled flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 when the static trial 100,1000 or disc 160 is held by the

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

inserter/impactor 400,4000. For example, in an anterior approach for the trial 100,1000 (as shown in ~~Figs. 4e-h~~ Figs. 59-62 as an example of how either trial 100,1000 can be held by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420a (or 4200a and 4200d), 120b,1200b and 120e,1200e facing 420b (or 4200b and 4200e), and 120c,1200c and 120f,1200f facing 420c (or 4200c and 4200f), and in an anterior approach for the disc 160 (as shown in ~~Figs. 4k-n~~ Figs. 65-68), 180a and 180d facing 420a (or 4200a and 4200d), 180b and 180e facing 420b (or 4200b and 4200e), and 180c and 180f facing 420c (or 4200c and 4200f).

[00150] It should be noted that preferably, when the static trial 100,1000 is held by the inserter/impactor 400,4000, the flat surfaces 120a-c,1200a-c and the counterpart flat surfaces 120d-f,1200d-f are tightly held against the angled flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 as described above. It is also preferable that the baseplates 108a-b,1080a-b of each of the plurality of static trials 100,1000 be appropriately lordotically angled relative to one another to ease insertion of the static trial 100,1000 into the intervertebral space and to mimic how the artificial intervertebral disc 160 will typically be oriented as it is being inserted using the inserter/impactor 400,4000. While not shown in ~~Figs. 1a-f or Figs. 1aa-ff~~ Figs. 1-6 or Figs. 7-12, in some embodiments, when the static trials 100,1000 are formed in such a lordotically oriented configuration, it is preferable that the flat surfaces 120d-f,1200d-f on the first (e.g., upper) baseplate 108a,1080a be parallel to the flat surfaces 120a-c,1200a-c of the second (e.g., lower) baseplate 108b,1080b in the static trial's 100,1000 appropriately lordotically oriented configuration, so that when the static trial 100,1000 is held tightly by the inserter/impactor 400,4000, the flat surfaces 120a-f,1200a-f are flush with the flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 even though the baseplates 108a-b,1080a-b are lordotically oriented configuration, it is preferable that the flat surfaces 120d-f,1200d-f on the first (e.g., upper) baseplate 108a,1080a be parallel to the flat surfaces 120a-c,1200a-c of the second (e.g., lower) baseplate 108b,1080b in the static trial's 100,1000 appropriately lordotically oriented

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

configuration, so that when the static trial 100,1000 is held tightly by the inserter/impactor 400,4000, the flat surfaces 120a-f,1200a-f are flush with the flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 even though the baseplates 108a-b,1080a-b are lordotically angled with respect to one another.

[00153] Also preferably, in order to provide for a holding of the static trial 100,1000 or disc 160 for two additional (here, anteriolateral) insertion approaches, each static trial 100,1000 or disc 160 also includes two additional holes 122a,1220a,182a and 122c,1220c,182c, one (e.g., 122a,1220a,182a) spaced apart from one of the anteriolaterally facing flat surfaces (e.g., 120a,1200a,180a), and the other (e.g., 122c,1220c,182c) spaced apart from the other of the anteriolaterally facing flat surfaces (e.g., 120c,1200c,180c). Accordingly, operation of the inserter/impactor 400,4000 can fit the holding pin 408,4080 into either of these two additional holes 122a,1220a,182a or 122c,1220c,182c, and hold the associated anteriolaterally facing flat surface (the one associated with the hole into which the pin 408,4080 is fit) of the static trial 100,1000 or disc 160 against the flat surface of the inserter/impactor 400,4000 opposite the pin 408,4080. For example, in a first anteriolateral approach for the trial 100,1000 (as shown in ~~Fig. 4~~Fig. 63 as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d not confronted, 120b,1200b and 120e,1200e facing 420a (or 4200a and 4200d), and 120c,1200c and 120f,1200f facing 420b (or 4200b and 4200e), and a first anteriolateral approach for the disc 160 (as shown in ~~Fig. 4~~Fig. 69 as an example of the how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d not confronted, 180b and 180e facing 420a (or 4200a and 4200d), and 180c and 180f facing 420b (or 4200b and 4200e). And, for example, in a second anteriolateral approach for the trial 100 (as shown in ~~Fig. 4~~Fig. 64 as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420b (or 4200b and 4200e), 120b,1200b and 120e,1200e facing 420c (or 4200c and 4200f), and 120c,1200c and 120f,1200f not confronted, and a second anteriolateral approach for the

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

disc 160 (as shown in ~~Fig. 4p~~Fig. 70 as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420b (or 4200b and 4200e), 180b and 180e facing 420c (or 4200c and 4200f), and 180c and 180f not confronted.

[00159] Referring now to ~~Figs. 5a-e~~Figs. 83-85, a symmetric repositioner/extractor of the present invention is shown in side (~~Fig. 5a~~Fig. 83), top (~~Fig. 5b~~Fig. 84), and perspective (~~Fig. 5c~~Fig. 85) views. And referring now to ~~Figs. 5d-f~~Figs. 86-88, an offset left repositioner/extractor of the present invention is shown in side (~~Fig. 5d~~Fig. 86), top (~~Fig. 5e~~Fig. 87), and perspective (~~Fig. 5f~~Fig. 88) views. And referring now to ~~Figs. 5g-i~~Figs. 89-91, an offset right repositioner/extractor of the present invention is shown in side (~~Fig. 5g~~Fig. 89), top (~~Fig. 5h~~Fig. 90), and perspective (~~Fig. 5i~~Fig. 91) views. And referring now to ~~Figs. 5j-l~~Fig. 92-94, an alternative offset left repositioner/extractor of the present invention is shown in side (~~Fig. 5j~~Fig. 92), top (~~Fig. 5k~~Fig. 93), and perspective (~~Fig. 5l~~Fig. 94) views. And referring now to ~~Figs. 5m-o~~Figs. 95-97, an alternative offset right repositioner/extractor of the present invention is shown in side (~~Fig. 5m~~Fig. 95), top (~~Fig. 5n~~Fig. 96), and perspective (~~Fig. 5o~~Fig. 97) views.

[00164] The first, symmetric, repositioner/extractor 500, shown in ~~Figs. 5a-e~~Figs. 83-85, includes a shaft 502 having a distal end that is symmetrically divided into two prongs 504a-b, each of the prongs having a pin 506a-b extending upwardly and parallel to the pin on the other prong. The second and third, left offset and right offset, repositioners/extractors 510,520, shown in ~~Figs. 5d-f~~Figs. 86-88 and ~~5g-i~~89-91, respectively, each include a shaft 512,522 having a distal end that bends diagonally laterally, the left offset distal end 514 bending in one direction (e.g., to the left), the right offset distal end 524 bending in an opposite direction (e.g., to the right). The distal end of each of the second and third repositioners/extractors 510,520 has two pins 516a-b,526a-b serially spaced on the bent portion, and each of the pins extends upwardly

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

and parallel to the other pin. (As shown in ~~Figs. 5j-1~~Figs. 92-94 and ~~5m-e~~95-97, alternative embodiments 530,540 of the second and third, left offset and right offset, repositioners/extractors each include a shaft 532,542 having a distal end that has a straight prong 534a,544a and a curved lateral prong 534b,544b, where the curved lateral prong 534b extends in one direction (e.g., left) for the alternative left offset repositioner/extractor 530, and where the curved lateral prong 544b extends in an opposite direction (e.g., right) for the alternative right offset repositioner/extractor 540. Each of the prongs 534a-b,544a-b has a pin 536a-b,546a-b extending upwardly and parallel to the pin on the other prong. The alternative repositioners/extractors 530,540, each having a space between the pins 536a,b,546a,b, provides for avoidance of any structures on the static trial or artificial intervertebral disc that may be present between the holes.) On each of the repositioners/extractors 500,510,520,530,540, the pins are spaced so that they simultaneously each fit into a respective one of the two adjacent holes in the baseplate of the static trial or artificial intervertebral disc. Each of the repositioners/extractors 500,510,520,530,540 has a handle 508,518,528,538,548 at a proximal end of the central shaft which is useful for pushing or pulling on the shaft, and a flange 509,519,529,539,549 adjacent the proximal end of the shaft that is useful for impaction (either with a distally directed force or a proximally directed force), if necessary to manipulate the shaft.

[00165] As noted above, the repositioner/extractor that is appropriate or desired for a given case depends at least in part on the configuration of the holes in the baseplates. Two hole configurations are disclosed, as examples of suitable configurations, although other configurations are possible and contemplated by the present invention. A first hole configuration includes three holes on one of the baseplates, the holes being configured so that a first hole is located in the anterior-posterior plane, and the adjacent (second and third) holes are located in respective opposing anteriolateral planes on either side of the first hole. This hole configuration is shown in ~~Figs. 5p-u~~Figs. 98-103, each of which shows a top cutaway view of the

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

artificial intervertebral disc of ~~Figs. 1g-n~~Figs. 13-20, showing its lower baseplate, having the first hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the lower baseplate shows the first hole 550, the second hole 552, and the third hole 554 of the first hole configuration.

[00166] A second hole configuration includes four holes on one of the baseplates, the holes being configured so that first and second holes straddle the anterior-posterior plane, a third hole is located so that the third hole and the first hole straddle one of the opposing anteriolateral planes, and a fourth hole is located so that the fourth hole and the second hole straddle the other of the opposing anteriolateral planes. This hole configuration is shown in ~~Figs. 5v-dd~~Figs. 104-112, each of which shows a bottom cutaway view of the artificial intervertebral disc of ~~Figs. 1g-n~~Figs. 13-20, showing its upper baseplate, having the second hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the upper baseplate shows the first hole 560, the second hole 562, the third hole 564, and the fourth hole 566, of the second hole configuration.

[00168] As noted above, and referring now to ~~Figs. 5p-dd~~Figs. 98-112, it can be seen that each of the repositioner/extractors can be used in more than one manner depending on the tool desired and the approach desired. For example, with reference to ~~Figs. 5p-q~~Figs. 98-99, regarding the first hole configuration (three holes in one of the baseplates), the symmetric repositioner/extractor 500 can be used in either of two anteriolateral approaches (see ~~Figs. 5p-q~~Figs. 98-99). That is, the symmetric repositioner/extractor's shaft 502 can be inserted into the wound from either of the two anteriolateral approaches, and the pins 506a-b can be inserted into the first 550 and second 552 holes (for one of the two anteriolateral approaches) (~~Fig. 5p~~Fig. 98) or the first 550 and third 552 holes (for the other of the two anteriolateral approaches) (~~Fig. 5q~~Fig. 99) of the first hole configuration.

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

[00169] Also, for example, with reference to ~~Figs. 5r-u~~Figs. 100-103, regarding the first hole configuration, each of the left offset repositioner/extractor 510 and the right offset repositioner/extractor 520 can be used in either a directly anterior approach (~~Figs. 5r,t~~Figs. 100,102) or a respective anteriolateral approach (~~Figs. 5s,u~~Figs. 101,103). That is, the right offset repositioner/extractor's shaft 522 can be inserted into the wound from a direct anterior approach, and the right offset repositioner/extractor's pins 526a-b can then be placed into the first 550 and second 552 holes of the first hole configuration (~~Fig. 5r~~Fig. 100). And, the right offset repositioner/extractor's shaft 522 can be inserted into the wound from an anteriolateral approach, and the right offset repositioner/extractor's pins 526a-b can then be placed into the first 550 and third 554 holes of the first hole configuration (~~Fig. 5s~~Fig. 101). And, the left offset repositioner/extractor's shaft 512 can be inserted into the wound from a direct anterior approach, and the left offset repositioner/extractor's pins 516a-b can then be placed into the first 550 and third 554 holes of the first hole configuration (~~Fig. 5t~~Fig. 102). And, the left offset repositioner/extractor's shaft 512 can be inserted into the wound from an anteriolateral approach, and the left offset repositioner/extractor's pins 516a-b can then be placed into the first 550 and second 552 holes of the first hole configuration (~~Fig. 5u~~Fig. 103). It should be noted that the alternate left offset 530 and alternate right offset 540 repositioners/extractors can also fit into the holes of the first hole configuration in the same manner as described here with regard to the left offset 510 and right offset 520 repositioners/extractors.

[00170] Also, for example, with reference to ~~Figs. 5v-dd~~Figs. 104-112, regarding the second hole configuration (four holes in one of the baseplates), the symmetric repositioner/extractor 500 can be used in a directly anterior approach (~~Fig. 5v~~Fig. 104), and either of two anteriolateral approaches (~~Figs. 5w-x~~Figs. 105-106). That is, the symmetric repositioner/extractor's shaft 502 can be inserted into the wound from a directly anterior approach, and the pins 506a-b can be inserted into the first 560 and second 562 holes of the second hole configuration (~~Fig. 5v~~Fig. 104). And,

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

the symmetric repositioner/extractor's shaft 502 can be inserted into the wound from either of the two anteriolateral approaches, and the pins 506a-b can be inserted into the first 560 and third 564 holes (for one of the two anteriolateral approaches) (~~Fig. 5w~~Fig. 105) or the second 562 and fourth 566 holes (for the other of the two anteriolateral approaches) (~~Fig. 5x~~Fig. 106) of the second hole configuration.

[00171] Also, for example, with reference to ~~Figs. 5y-dd~~Figs. 107-112, regarding the second hole configuration, each of the left offset repositioner/extractor 510 and the right offset repositioner/extractor 520 can be used in any of three respective anteriolateral approaches. That is, the right offset repositioner/extractor's shaft 522 can be inserted into the wound from any of its three possible anteriolateral approaches, and the right offset repositioner/extractor's pins 526a-b can then be placed into the first 560 and second 562 holes (~~Fig. 5y~~Fig. 107) (for a first of the three anteriolateral approaches), the first 560 and third 564 holes (~~Fig. 5z~~Fig. 108) (for a second of the three anteriolateral approaches), or the second 562 and fourth 566 holes (~~Fig. 5aa~~Fig. 109) (for a third of the three anteriolateral approaches). And, the left offset repositioner/extractor's shaft 512 can be inserted into the wound from any of its three possible anteriolateral approaches, and the left offset repositioner/extractor's pins 516a-b can then be placed into the first 560 and second 562 holes (~~Fig. 5bb~~Fig. 110) (for a first of the three anteriolateral approaches), the first 560 and third 564 holes (~~Fig. 5cc~~Fig. 111) (for a second of the three anteriolateral approaches), or the second 562 and fourth 566 holes (~~Fig. 5dd~~Fig. 112) (for a third of the three anteriolateral approaches). It should be noted that the alternate left offset 530 and alternate right offset 540 repositioners/extractors can also fit into the holes of the second hole configuration in the same manner as described here with regard to the left offset 510 and right offset 520 repositioners/extractors.

[00172] It should be noted from the illustrations in ~~Figs. 5p-dd~~Figs. 98-112 that the anteriolateral approaches are at a variety of angles relative to the anterior-



**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

posterior plane, and further that the illustrated angles are merely exemplary. That is, the invention encompasses additional approach angles, in that such additional approach angles are possible by (as described above) adding or deleting holes, and/or changing the location of holes, and/or changing the spacing between holes (in conjunction with changing the spacing between pins), and/or changing the angle at which the offset repositioner/extractors' pins are placed relative to one another and to the shaft of such repositioner/extractors.

[00175] Referring now to ~~Figs. 6a-e~~Figs. 113-117, a leveler of the present invention is shown in bottom (~~Fig. 6a~~Fig. 113), side (~~Fig. 6b~~Fig. 114), front (~~Fig. 6c~~Fig. 115), top partial perspective (~~Fig. 6d~~Fig. 116), and bottom partial perspective (~~Fig. 6e~~Fig. 117) views. More particularly, ~~Fig. 6d~~Fig. 116 shows a top perspective view of the distal end of the leveler, and ~~Fig. 6e~~Fig. 117 shows a bottom perspective view of the distal end of the leveler.

[00179] More particularly, for example for use with the exemplary artificial intervertebral disc of ~~Figs. 1g-n~~Figs. 13-20, the upper surface 608a-b of each extent is flat, except for a tapered section 612a-b at the distal tip of the extent, which tapered section narrows the tip, and the lower surface 610a-b of each extent is curved to form opposing concave contours 614a-b that are cooperatively shaped to conform against the inwardly facing surface of the convex structure of the artificial intervertebral disc.

**Applicant(s):** Errico et al.  
**Serial No.:** 10/663,488  
**Filed:** 9/16/2003  
**For:** Intervertebral Spacer Device  
Having an Engagement Hole for  
Manipulation Using a Surgical  
Tool

**Examiner:** Not assigned  
**Art Unit:** 3738  
**Docket No.:** F-291  
**Dated:** 4/8/2004

### **DRAWING AMENDMENTS**

Please substitute the enclosed 27 drawings sheets for the 27 drawing sheets originally filed with the application.